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10/553,996	03/02/2007	Carmelo Francesco Melchi	2507-1074	6575

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YOUNG & THOMPSON
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EXAMINER

CONWAY, THOMAS A

ART UNIT	PAPER NUMBER
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2624

NOTIFICATION DATE	DELIVERY MODE
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06/23/2010

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

DocketingDept@young-thompson.com

Office Action Summary	Application No. 10/553,996	Applicant(s) MELCHI ET AL.	
	Examiner THOMAS A. CONWAY	Art Unit 2624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 19-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 19-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 October 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☒ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/21/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to because portions of the drawings are either illegible or does not make sense or display acronyms which are not sufficiently explained in the specification to allow a full understanding of the drawings, for example, Fig. 5. displays a diamond decision block with the term “Visual” in it. There are other writings following the term “Visual” that are not legible. Also, the flow leading from this block is not understood, specifically, the term “KO” – there are similar issues with Fig. 4 (block containing “Displaying are located by repere...”; Figs 6-10 and 13 have acronyms that are not explained and the specification does not develop the subject matter sufficiently. Drawings 1 and 2 are of an illegible quality. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as “amended.” If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as

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either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Priority

2. Acknowledgment is made of applicant's claim for priority based on a PCT application filed on April 15, 2004 with a foreign priority date of April 22, 2003 based on application RM2003A000184, filed in Italy. It is noted, however, that applicant has not filed a certified copy of the RM2003A000184 application. It is unclear whether the original application (RM2003A000184), as filed on Apr 22, 2003 fully supports the invention as currently claimed. Please submit a certified copy.

Specification

3. The disclosure is objected to because of the following informalities: The specification is silent with regards to the included Tables. Claimed limitations include reference to algorithms which are not presented anywhere in the specification.

Page 21 of the specification seems to be missing.

Appropriate correction is required.

Claim Objections

4. Claim 21 does not end in a period.

5. Claim 28 - there are two instances of the term “parametrization” - the Examiner believes these to be misspellings of “parameterization”.

6. Claim 29 – there is a term “grater” – the Examiner believes this is a misspelling of “greater”.

7. Claim 30 is objected to because of the following informalities: Contains two periods – see pg 8, after the “k” bullet . Appropriate correction is required.

8. Claim 32 recites the term “which” in reference to “an assistant”. The Examiner suggests amending this term to be "whom".

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28, 29, 31, 34 and 36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in

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the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically:

- a. Claim 28 – no details are given in the specification with regards to “ablating piliferous appendages...”, “constructing grey levels referred to the weight of blue”, constructing levels of identification..”, “calculating mathematically the evidence threshold”, for example that would enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention without undue experimentation.
- b. Claim 29 – several algorithms are recited but no details are given.
- c. Claims 28 and 29 will not be examined for the purposes of prior art since neither of the claims have recitations that are clear enough as to be understood by the Examiner.
- d. Claim 31 – no details are given that would enable one skilled in the art to “**guarantee** a correct collimation of the collected images”.
- e. Claim 34 – no details are given that would enable one skilled in the art to ensure that “corresponding images are collected in the following sessions **exactly** with the same position and orientation”.

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f. Claim 36 – recites a minimum where zero overlap occurs. This is not supported by the specification or enabled. In fact, it seems as if this minimum would contradict the essence of the invention as claimed since no registering landmarks would occur in an overlap in order to allow for identification and registration of lesions according to landmarks co-occurring in overlapped images.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. **Regarding claim 19**, the word "means" is proceeded by the words "spatial coordinates" in an attempt to use a "means" clause to recite a claim element as a means for performing a specified function. However, since no function is specified by the word(s) proceeding "means," it is impossible to determine the equivalents of the element, as required by 35 U.S.C. 112, sixth paragraph. See *Ex parte Klumb*, 159 USPQ 694 (Bd. App. 1967).

10. **Claims 19, 20, 22-26, 28-31, 33-34 and 36 are rejected under 35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, for example:

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- g. Claim 19 – lines 3-5 do not make sense to the Examiner as currently written, for example “transmission of said variations digital images”.
- h. Claim 19 - line 6, it is unclear what the term “latter” is referring to.
- i. Claim 20 – the term “suitable size” is indefinite.
- j. Claim 20 – it is unclear to what “the following detection” is referring to.
- k. Claim 20 – there are instances of “**and/or**” which the Examiner deems to be indefinite. **There are multiple instances of this phrase throughout the claims which need to be addressed.**
- l. Claim 22 - it is unclear to what “the two preceding items” is referring to.
- m. Claim 23 – the use of parenthesized terms such as “or his/her skin portion” is deemed indefinite by the Examiner. **This type of recitation occurs throughout the claims. It is unclear whether the parenthesized terms are being presented as examples of the preceding terms, or as annotation of an acceptable acronym, an alternative or as a specifying term. These parenthesized terms need to be amended so that their encompassed terms are presented in a manner that will be understood in relation to preceding**

or proceeding associated terms. This type of recitation occurs in at least claims 28-30 and 36.

- n. Claim 24 - the term “essentially” is indefinite.
- o. Claim 25 – it is unclear to what “comparison” is referring to.
- p. Claim 25 – lines 2-3 do not seem to read properly, “the body surface of tested subject is segmented or subdivided into images is performed...”.
- q. Claim 25 – is it unclear what “modifications” are referring to.
- r. Claim 28 – there is a recitation of “not human pixels”; the Examiner believes that this limitation does not read as was intended, since all pixels are considered “not human” – therefore the limitation does not make sense as written.
- s. Claim 29 – it is unclear what “rotating/translating” is referring to.
- t. Claim 29 - there is mention of “dimensional variation”, “discards” and “erroneous connections” but no details in the claim or the specification as to what they refer to.

- u. Claim 29 – the phrase “greater than three of” is open ended – it is unclear what limitation is intended.
- v. Claim 31- the term “significant” is indefinite.
- w. Claim 33 - it is unclear what the term “latter” is referring to.
- x. Claim 34 – line 3 recites “the position and the orientation taken by said image collection means” but there is no previous mention of the image collection means taking position and orientation.
- y. Claim 36 – the term “preferably” is indefinite.
- z. Claim 36 – it is unclear to what image the term “image” refers to.

NOTE – these identified instances represent a sample of occurrence of indefiniteness in the current application. The Examiner suggests reviewing the entire claim language for like instances and making appropriate corrections.

11. Claim 19 recites the limitation "the number", "the morphology", "the external skin", "the detection", "the transmission", for example. There is insufficient antecedent

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basis for this limitation in the claim. There are many instances of lack of antecedent basis throughout this claim the Examiner has not listed. There are many instances of similar lack of antecedent basis in each and every claim. The Examiner suggests going through each and every claim to correct these multiple instances. **To reiterate, each and every claim (19-36) are being rejected for like instances of lack of antecedent basis.**

12. **Regarding claim 29**, the phrase "for example" renders the claim indefinite because it is unclear whether the limitation(s) following the phrase are part of the claimed invention. See MPEP § 2173.05(d).

13. **Claims 22 and 28 are rejected under 35 U.S.C. 112, second paragraph**, as being indefinite in that it fails to point out what is included or excluded by the claim language. This claim is an omnibus type claim. Specifically, each claim recites "etc". There may be other instances of this term – please make the appropriate corrections.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 19-21, 23, 25-27 and 30-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Craine et al. (US 6,427,022 B1: hereafter “Craine”).

14. **Regarding claim 19**, Craine discloses a method of detecting and showing variations in the number and/or the morphology of the external skin lesions of dermatological interest (Fig 7, shape and size varied over time), characterized in that in order to automate the detection (Col. 8, ln 3-13, for example, image subtraction) and the transmission of said variations digital images of the body surface of the tested subject (Col. 8, ln 3-13, registration – images are transmitted to and from database) are collected after having divided the latter into one or more areas exactly located by means of spatial coordinates in a system of coordinated axes fixed with respect to predetermined unchanged reference points of the subject (Figs 2A-D and Fig 3: using skin landmarks as matching points, subdividing body surface), the images being stored in a suitable data base to be then compared automatically with corresponding images collected at distance of time, (Col. 3, ln 18-43), thus producing a signal of any variation in the number and/or the morphology/colour of the lesions (Fig 7 – See also Col 6, ln 2-17, using a CCD camera); the relative spatial position between the subject body surface and the point of view from which said images are collected being the same for each subsequent corresponding image (Fig 5, item 9C).

15. **Regarding claim 20**, Craine discloses the method according to claim 19, characterized in that there are provided the following operating steps: A. subdividing the

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body surface into quadrants with suitable size (Figs 2A-D); B. selecting predetermined reference or "repere" anatomic points so that the following detection may have repere points able to collimate the body quadrants of the same subject (Figs 2A-D, skin landmarks are used as matching points); C. collecting and storing images with high definition relative to the above-mentioned quadrants (Fig 7 – See also Col 6, In 2-17, using a CCD camera); D. processing the stored images to perform the following operations: - locating, numbering and measuring all of the skin lesions present in each quadrant (Col 3, In 23-26: "identify" or measure", identification of a lesion inherently includes the lesion into a lesion category, which is considered "numbering" in the broadest reasonable understanding of the term); storing images and data relative to said skin lesions; if the subject is not a new subject, comparing collected images and corresponding data with previously stored images and data of the same subject (Figs 6A and 6B, comparator program); - highlighting and/or transmitting the new skin lesions in each quadrant and/or highlighting the morphological/colorimetric variations in one or more previously located skin lesions; - storing data relative to the detected differences (Fig 7, morphological variation is highlighted).

16. **Regarding claim 21**, Craine discloses the method according to claim 19, characterized in that there are provided the following steps: a) inputting anthropometrical data of the subject to be tested (Col 5, In 16-24, baseline image information is loaded, identification information is also entered); b) selecting the portion(s) of the body surface to be detected (Figs 2A-D); c) positioning the subject on

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the basis of the predetermined reference and/or repere points (Fig 5, uses distance from camera and body surface landmarks); d) calculating the coordinates of the center of each image and the direction of collection of each of them (Figs 2A-D, the centers of the quadrants are identified);

e) collecting and storing said images automatically and repeatedly (Fig 6B, iterative step of saving image into comparator program); f) analyzing the stored images to locate the existing skin lesions of interest (Col 7, ln 17-24); g) comparing the analysed images with the images stored and analysed previously, if any, to highlight the presence of any numeric and/or colorimetric difference (Fig 7, larger lesion represents measurable variance – See also Col 8, ln 9-21, “subtraction”).

17. **Regarding claim 23**, Craine discloses the method according to claim 19, characterized in that in order for any variation of the collected images not relating the state of the skin lesions to be suppressed or minimized, it is provided that each skin portion of the same subject is detected in subsequent times from a predetermined and fixed point of view, or that the spatial positions of the detection apparatus and the tested subject (or his/her skin portion) are constant (Fig 5, item 9C).

18. **Regarding claim 25**, Craine discloses the method according to claim 23, characterized in that the body surface of tested subject is segmented or sub\divided into images is performed so that the edges of the images are partially overlapped so as

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to allow a comparison even when modifications of the body of the tested subject take place between subsequent tests (Figs 2A-D).

19. **Regarding claim 26**, Craine discloses the method according to claim 25, characterized in that the number of collected images for a determined patient is always the same, even if the patient increase in weight and/or height in time (Figs 2A-D, fixed set of numbered images).

20. **Regarding claim 27**, Craine discloses the method according to claim 19, characterized in that the patient is illuminated uniformly and from different angles so as to avoid portions in the shade at the areas to be detected (Fig 1).

21. **Claim 30** is rejected for at least the same reasoning as was previously presented with regards to claim 19.

22. **Claim 31** is rejected for at least the same reasoning as was previously presented with regards to claim 19.

23. **Regarding claim 32**, Craine discloses the apparatus according to claim 31, characterized in that it is provided with a computer, controlled by an assistant, which controls and manages the apparatus in a completely automatic way (Col 5, ln 14-39).

24. **Regarding claim 33**, Craine discloses the apparatus according to claim 30, characterized in that said support and drive means of the image collection means is able to position the latter perpendicular to the area of the body surface to be detected and at a constant distance therefrom (Figs 5 and 1).

25. **Regarding claim 35**, Craine discloses the apparatus according to claim 30, characterized in that it is provided with calculating means which calculate the positions of the images to be collected, so that the edges of images adjacent to one another are partially surmounted, thus forming an overlap (Figs 2A-D).

26. **Regarding claim 36**, Craine discloses the apparatus according to claim 35, characterized in that the overlap of the image edges adjacent to one another varies preferably from a maximum equal to half the height and half the width of the image to a minimum that can be zero (images with coincident edges) (Figs 2A-D, the limitation of a minimum zero is not being given any weight since the Examiner believes that this recitation is not enabled – See previously presented 112 1st rejection).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

27. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 22, 24 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Craine in view of Kenet et al. (US 5,836,872: hereafter "Kenet").

28. **Regarding claim 22**, Craine discloses the method according to claim 20, but fails to teach: - locating objects contained in the image other than skin (underwear,

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background, etc.); - locating structures that can produce false positives (hairs, spots produced by natural orifices or shadows, tattoos, etc.); and - locating lesions of interest to be compared and ignoring objects and/or structures of the two preceding items.

Kenet, in the same field of endeavor of identifying skin lesions by comparing time lapsed images, teaches - locating objects contained in the image other than skin (underwear, background, etc.); - locating structures that can produce false positives (hairs, spots produced by natural orifices or shadows, tattoos, etc.); and - locating lesions of interest to be compared and ignoring objects and/or structures of the two preceding items (Col 18, ln 40-47).

To analyze lesions, identification of foreground lesions as opposed to background or skin must be distinguished. However, hairs may interfere with this type of segmentation by making lesion boundaries distorted or by falsely being identified as a lesion.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use the known technique of locating and removing structures that might produce false positives, such as hairs in order to ignore them in analyzing actual lesions of interest over time lapsed image comparison, as suggested by Kenet, to improve the similar method of Craine to yield the predictable result of improving lesion detection accuracy.

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29. **Regarding claim 24**, Craine discloses the method according to claim 23, but fails to teach that the tested subject is allowed to sit down to essentially the same position in any test following the first.

Kenet, in the same field of endeavor of identifying skin lesions by comparing time lapsed images, teaches that the tested subject is allowed to sit down to essentially the same position in any test following the first (Col 5, ln 35-40, "sitting").

While localizing lesions on a body surface, there may be an actual area of note such as a torso. Specifying the area to concentrate on the torso would allow for greater analysis of the area under test by having more images related with more landmarks over a smaller area. In the case that a torso is imaged, it would be obvious to position a subject under test in such a way as to facilitate image capture, such as having one sit in a seated position.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to try choosing from a finite number of positions of a subject under test to facilitate imaging of lesions of a region of a body that might benefit from a subject being in a seated position as suggested by Kenet and applying that to the method of Craine, with reasonable expectation of success.

30. **Regarding claim 34**, Craine discloses the apparatus according to claim 30 but fails to teach a storing means which store the position and the orientation taken by said image collection means for each collected image, during the first session so that corresponding images are collected in the following sessions exactly with the same

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position and orientation, thus providing following images perfectly corresponding and comparable with those of the preceding session.

Kenet, in the same field of endeavor of identifying skin lesions by comparing time lapsed images, teaches a storing means which store the position and the orientation taken by said image collection means for each collected image, during the first session so that corresponding images are collected in the following sessions exactly with the same position and orientation, thus providing following images perfectly corresponding and comparable with those of the preceding session (Col 4, ln 15-18).

Tracking position and orientation of an image device with relation to a subject body surface under test would allow for repeatability in imaging a particular body surface region and would allow for improved processing speed and use of less processing resources in registering overlapped images, thus making lesion analysis more efficient.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to use the known technique of storing the position and the orientation taken by an image collection means for each collected image, during the first session so that corresponding images are collected in the following sessions exactly with the same position and orientation, thus providing following images perfectly corresponding and comparable with those of the preceding session, as suggested by Kenet and apply it to the method of Craine, in order to improve the lesion analysis process to yield predictable results of making the method more processor efficient.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to THOMAS A. CONWAY whose telephone number is (571)270-5851. The examiner can normally be reached on Monday through Friday 8AM - 5PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Matthew Bella can be reached on 571-272-7778. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Thomas A. Conway/
Examiner, Art Unit 2624

/Tom Y Lu/
Primary Examiner, Art Unit 2624